SOLVAY SOLEXIS

8EHQ-11-18263

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EPA East – Room 6428
(Attn: TSCA Section 8(e) Coordinator)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

[redacted]

Re: Solvay Solexis, Inc.; TSCA Section 8(e) Submission for [redacted])

Dear Sir or Madam:

Solvay Solexis, Inc. ("Solexis") hereby submits to the U.S. Environmental Protection Agency ("EPA") under section 8(e) of the Toxic Substances Control Act ("TSCA") information regarding a four-week oral toxicity study in rats using the test substance [redacted], with Chemical Abstracts Service Registry Number ("CASRN") [redacted].

[redacted] studied the oral toxicity of [redacted] when administered daily to rats over a period of four consecutive weeks. Data also includes observation of recovery from any potential treatment-related effects over a period of two consecutive weeks. Three groups, each of five male and five female Sprague Dawley rats, received the test item by gavage at dosages of 0.3, 0.8 and 2.0 mg/kg/day for four consecutive weeks. Observations were recorded during dosing and at necropsy. See attachment 1 for a summary of the results.

If you have any questions regarding this submission, please do not hesitate to contact Sandra Podolak at (856) 251-3492 or Sandra.Podolak@solvay.com

Sincerely,

Laird McBeth, President
Solvay Solexis, Inc.

Enclosure- Attachment 1

88110000147

cc: Philip Milton, EPA HQ
Linda Longo, EPA Region 2
Sandra Podolak, Solvay Solexis Inc.

[redacted]

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Attachment 1

Summary of Results

[redacted] studied the oral toxicity of [redacted] when administered daily to rats over a period of four consecutive weeks. Data presented also include observation of recovery from any potential treatment-related effects over a period of two consecutive weeks. Three groups, each of five male and five female Sprague Dawley rats, received the test item by gavage at dosages of 0.3, 0.8 and 2.0 mg/kg/day for four consecutive weeks. Observations were recorded during dosing and at necropsy.

Data present signs of dose-related adverse toxic effects, some of which were not reversible up to two weeks following termination of exposure. The main target organ is the liver, findings reported were: hepatocytic, hypertrophy, and necrosis observed only in some males of the high and intermediate dose groups. Only partial remissions of such changes were observed in animals after recovery period. Lung toxicity (characterized by macrophage aggregation); thymus toxicity (characterized by atrophy); and reproductive organ toxicity (manifested by seminal vesicle colloid depletion) were observed in the high dose animals with almost complete remission after the 2 week recovery period. The last two changes could be considered secondary effects related to the general poor conditions of the high dose treated animals. Blood toxicokinetic analyses were carried out after single oral dose of 2.0 mg/kg; the half lives were higher in males than in females.

[redacted]

[redacted]

1. On its own behalf, Solvay Solexis, Inc. ("Solexis") submits the following substantiation of its claims to hold to the testing laboratory, the study number, the trade name of substance, and the Chemical Abstracts Service Registry Number ("CASRN") confidential.

2. The information claimed as confidential should be held confidential indefinitely, *i.e.,* until this technology is obsolete, or until the information is widely known. As discussed below, disclosure prior to this time could result in commercial detriment to Solexis.

3. Solexis has not disclosed the information claimed confidential to any other Federal agency other than the United States Environmental Protection Agency (USEPA). The substance name and CASRN were disclosed to the USEPA in the low volume exemption application but were claimed as confidential.

4. This information has been held strictly confidential and has not been disclosed to persons outside of Solexis, except that this information has been disclosed to outside legal counsel who appropriately protect its confidential status. Future disclosures also will be restricted. To prevent undesired disclosure by Solexis employees, Solexis requires that employees sign an agreement prohibiting disclosure of this and other proprietary information.

5. Solexis securely guards the information by not disclosing the specific chemical identity of the substance used for manufacture in the United States to third parties, except under non-disclosure agreements or to those who otherwise protect the confidentiality of this information.

6. The information claimed as confidential does not appear in advertising or promotional materials, or other similar materials, professional or trade publications, or any other media available to the public or competitors. The substance CASRN appears on internal Solexis MSDSs for the substance. These MSDS are for internal Solexis use only and are not distributed outside the use/processing site.

Otherwise, the substance CASRN appears on Solexis MSDSs only as referring to an impurity in Solexis products in a product line different than those product lines made using substance imported under the Low Volume Exemption. These product lines are manufactured outside the U.S., or are manufactured in the U.S. by compounding material imported into the U.S. which contains the substance only as an impurity.

7. No Federal agency or court has ruled on the confidentiality of this information.

8. Disclosure of this information would likely result in substantial harm to Solexis's competitive position. Currently, the information claimed as confidential cannot be ascertained without a major research effort.

[redacted]

9. Solexis has been granted patents and has pending patent applications which describe the use of this class of compounds used as a raw material for manufacturing polymers. However, the specific compound is not identified by CASRN number, molecular weight, chemical name or structure in these patents or patents information.

10. The substance is not commercially available in the United States. It is imported only by Solexis for use as a proprietary raw material in the manufacture of polymers.

11. Reverse engineering of this substance would be very difficult requiring a major long-term research effort. Because trace impurities of this substance in the finished product are nearly zero it would be very difficult to ascertain the identity of the substance.

12. Disclosure of this information would reveal a confidential manufacturing process. The substance is used as a proprietary raw material used in the manufacture of polymers. Disclosure of this information would likely result in substantial harm to Solexis's competitive position.

13. The Chemical Abstract Service Registry Number is [redacted].

14. The substance or any information claimed CBI is not the subject of FIFRA regulation or reporting.

[redacted]

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[redacted]